

# **EXHIBIT 17**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

_____	)	
DePuy Mitek, Inc.	)	
	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 04-12457 PBS
	)	
Arthrex, Inc.,	)	
	)	
Defendant.	)	
_____	)	

**ARTHREX, INC.'S ANSWER AND COUNTERCLAIM IN RESPONSE  
TO DEPUY MITEK, INC.'S AMENDED COMPLAINT**

Defendant Arthrex, Inc. ("Arthrex") responds to the Amended Complaint filed by Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") as follows:

**Parties, Jurisdiction and Venue**

1. The Complaint purports to bring an action for patent infringement. The remaining allegations of paragraph 1 assert legal conclusions that do not require a response.

2. Admitted.

3. Admitted.

4. Arthrex has insufficient information to admit or deny the allegations of paragraph 4 and therefore denies those allegations.

**Answer to Depuy Mitek's Claim for Relief**

5. Arthrex admits that U.S. Patent No. 5,314,446 ("the '446 patent") entitled "Sterilized Heterogeneous Braids" is attached as Exhibit A to the Complaint,

and that it issued on May 24, 1994 listing Ethicon as the assignee on the cover page. Arthrex has no knowledge or information sufficient to confirm whether Ethicon, Inc. assigned the '446 patent to DePuy Mitek and therefore denies the same. Arthrex denies that the patent was duly and legally issued by the U.S. Patent and Trademark Office.

6. Arthrex admits that it sells sutures under the trade name FiberWire™ in the United States, including within this judicial district, but denies each and every other allegation contained in paragraph 6 of the Amended Complaint.

7. Arthrex denies each and every allegation contained in paragraph 7 of the Amended Complaint.

8. Arthrex admits that it was involved in the design, development and commercialization of FiberWire™ and TigerWire® sutures and that at least some of those products would be sold in the United States. Arthrex denies the remaining allegations of paragraph 8 of the Amended Complaint.

9. Arthrex denies each and every allegation contained in paragraph 9 of the Amended Complaint.

10. Arthrex has insufficient information to admit or deny the allegations of paragraph 10 and therefore denies those allegations.

11. Arthrex denies each and every allegation contained in paragraph 11 of the Amended Complaint.

FURTHER ANSWERING, Arthrex presents the following affirmative defenses:

**AFFIRMATIVE DEFENSES**

12. The '446 patent is invalid under 35 U.S.C. § 102.
13. The '446 patent is invalid under 35 U.S.C. § 103.
14. The '446 patent is invalid under 35 U.S.C. § 112.

15. Arthrex does not now infringe and has not infringed the '446 patent either literally or under the doctrine of equivalents.

16. Arthrex does not now induce and has not induced others to infringe the '446 patent either literally or under the doctrine of equivalents.

17. By virtue of DePuy Mitek's unreasonable and unjustified delay in bringing the present lawsuit to the prejudice of Arthrex, recovery is barred under the doctrine of laches.

18. Upon information and belief, the '446 patent is unenforceable due to inequitable conduct committed before the U.S. Patent and Trademark Office ("the Patent Office") during prosecution of the application which eventually issued as the '446 patent for the following reasons, among others.

19. During prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from the claims of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bio-absorbable yarns. Kaplan, however, does not always contain a bio-absorbable portion and discloses a combination of non-bio-absorbable yarns.

20. During the prosecution of the '511 application, applicants and their attorneys responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction would have poor qualities for a

suture and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys believed that high tensile polythene was included within their claimed invention, then they could not have truthfully made these statements and representations to the examiner.

21. The applicants and their attorneys acted with intent to deceive the Patent Office since they knew or should have known that their statements were false and misleading and that the Patent Office would rely on such statements in reconsidering the rejections in light of Kaplan and Burgess. In fact, following the applicants' and their attorneys' misrepresentations and mischaracterizations of Kaplan and Burgess, the '511 application was allowed and eventually issued as the '446 patent.

22. DePuy Mitek, by virtue of its efforts to obtain, enforce and use the '446 patent, knowing said patent to be invalid, unenforced, and unenforceable, have misused said patent, whereby DePuy Mitek is precluded from enforcing the same against Arthrex.

### **COUNTERCLAIM**

1. Arthrex, is a corporation organized under the laws of the State of Delaware, with its corporate headquarters and principal place of business at 1370 Creekside Boulevard, Naples, Florida 34108.

2. DePuy Mitek is a corporation organized under the laws of the State of Massachusetts, with its corporate headquarters and principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts 02062.

3. Arthrex repeats and realleges and incorporates herein by reference, paragraphs 12-22 of its Affirmative Defenses.

4. This is a claim arising under the Patent Laws of the United States, Title 35, United States Code, for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202. The jurisdiction of this Court is founded upon 28 U.S.C. §§ 1338(a), 2201 and 2202.

5. DePuy Mitek alleges that it is the owner of the '446 patent. There exists an actual controversy between Arthrex and DePuy Mitek with respect to the validity, enforceability, scope and infringement of the '446 patent.

6. The '446 patent is not infringed, and further is invalid and unenforceable at least for the reasons set forth in paragraphs 12-22 of Arthrex's Affirmative Defenses.

7. Arthrex seeks a declaration by the Court that the '446 patent is not infringed, either directly or by inducement, by Arthrex, that the '446 patent is invalid and unenforceable, and that DePuy Mitek, knowing that the '446 patent is invalid, not infringed by Arthrex and unenforceable, while asserting the patent against Arthrex, has committed patent misuse.

8. DePuy Mitek's conduct renders this an exceptional case within the provisions of 35 U.S.C. § 285, and Arthrex is accordingly entitled to an award of attorneys' fees.

WHEREFORE, Arthrex prays for judgment against DePuy Mitek as follows:

A. That the Court deny all relief to DePuy Mitek, and that the Amended Complaint be dismissed with prejudice;

B. That the Court decree, adjudge and declare that the '446 patent is invalid, not infringed by Arthrex, directly or through inducement, and unenforceable and that DePuy Mitek has committed patent misuse by knowingly asserting an invalid

and unenforceable patent against Arthrex, with knowledge that Arthrex does not infringe said patent;

C. That the Court find this an exceptional case and award reasonable attorney fees to Arthrex under 35 U.S.C. § 285;

D. That the Court award Arthrex its costs, and expenses; and

E. That the Court grant such further relief as it deems just and proper.

**JURY DEMAND**

Arthrex demands a trial by jury on all issues triable to a jury with respect to its counterclaim.

Dated: September 26, 2005

Respectfully submitted,

By: s/Charles W. Saber

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Salvatore P. Tamburo  
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Counsel for Defendant  
Arthrex, Inc.



**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Arthrex, Inc.'s Answer and Counterclaim in Response to DePuy Mitek, Inc.'s Amended Complaint was served via overnight courier on September 26, 2005, upon the following counsel for DePuy Mitek, Inc.:

Dianne B. Elderkin, Esq.  
Lynn A. Malinoski, Esq.  
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s/Salvatore P. Tamburo

# **EXHIBIT 18**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.	)	
	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 04-12457 PBS
	)	
Arthrex, Inc.,	)	
	)	
Defendant.	)	

**PEARSALLS LIMITED'S ANSWER AND COUNTERCLAIM IN RESPONSE  
TO DEPUY MITEK, INC.'S AMENDED COMPLAINT**

Defendant Pearsalls Limited ("Pearsalls") responds to the Amended Complaint filed by Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") as follows:

**Parties, Jurisdiction and Venue**

1. The Complaint purports to bring an action for patent infringement. The remaining allegations of paragraph 1 assert legal conclusions that do not require a response.

2. Admitted.
3. Admitted.
4. Admitted.

**Answer to Depuy Mitek's Claim for Relief**

5. Pearsalls admits that U.S. Patent No. 5,314,446 ("the '446 patent") entitled "Sterilized Heterogeneous Braids" is attached as Exhibit A to the Complaint, and that it issued on May 24, 1994 listing Ethicon as the assignee on the cover page.

Pearsalls has no knowledge or information sufficient to confirm whether Ethicon, Inc. assigned the '446 patent to DePuy Mitek and therefore denies the same. Pearsalls denies that the patent was duly and legally issued by the U.S. Patent and Trademark Office.

6. Pearsalls admits that Arthrex sells sutures under the trade name FiberWire™ in the United States, including within this judicial district, but denies each and every other allegation contained in paragraph 6 of the Amended Complaint.

7. Pearsalls denies each and every allegation contained in paragraph 7 of the Amended Complaint.

8. Pearsalls admits that it was involved in the design, development and commercialization of FiberWire™ and TigerWire® sutures and that at least some of those products would be sold in the United States. Pearsalls denies the remaining allegations of paragraph 8 of the Amended Complaint.

9. Pearsalls has insufficient information to admit or deny the allegations of the first sentence of paragraph 9 and therefore denies those allegations. Pearsalls denies the remaining allegations of paragraph 9.

10. Pearsalls admits the allegations of paragraph 10 of the Amended Complaint.

11. Pearsalls denies each and every allegation contained in paragraph 11 of the Amended Complaint.

FURTHER ANSWERING, Pearsalls presents the following affirmative defenses:

### **AFFIRMATIVE DEFENSES**

12. The Court lacks personal jurisdiction over Pearsalls since Pearsalls does not reside within this judicial district and DePuy Mitek has failed to allege that Pearsalls engages in business activity within this judicial district sufficient to vest this Court with personal jurisdiction over Pearsalls.

13. Service was insufficient because, upon information and belief, service of process was not performed in compliance with Rule 4(f) of the Federal Rules of Civil Procedure.

14. The '446 patent is invalid under 35 U.S.C. § 102.

15. The '446 patent is invalid under 35 U.S.C. § 103.

16. The '446 patent is invalid under 35 U.S.C. § 112.

17. Pearsalls does not now infringe and has not infringed the '446 patent either literally or under the doctrine of equivalents.

18. Pearsalls does not now induce and has not induced others to infringe the '446 patent either literally or under the doctrine of equivalents.

19. Upon information and belief, the '446 patent is unenforceable due to inequitable conduct committed before the U.S. Patent and Trademark Office ("the Patent Office") during prosecution of the application which eventually issued as the '446 patent for the following reasons, among others.

20. During prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from the claims of the '511 application. For example, in response to rejections on anticipation and obviousness

grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bio-absorbable yarns. Kaplan, however, does not always contain a bio-absorbable portion and discloses a combination of non-bio-absorbable yarns.

21. During the prosecution of the '511 application, applicants and their attorneys responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction would have poor qualities for a suture and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys believed that high tensile polythene was included within their claimed invention, then they could not have truthfully made these statements and representations to the examiner.

22. The applicants and their attorneys acted with intent to deceive the Patent Office since they knew or should have known that their statements were false and misleading and that the Patent Office would rely on such statements in reconsidering the rejections in light of Kaplan and Burgess. In fact, following the applicants' and their attorneys' misrepresentations and mischaracterizations of Kaplan and Burgess, the '511 application was allowed and eventually issued as the '446 patent.

23. DePuy Mitek, by virtue of its efforts to obtain, enforce and use the '446 patent, knowing said patent to be invalid, unenforced, and unenforceable, have misused said patent, whereby DePuy Mitek is precluded from enforcing the same against Pearsalls.

### COUNTERCLAIM

1. Pearsalls is a private limited company organized under the laws of the United Kingdom with a principal place of business at Tancred Street, Taunton, Somerset TA1 1RY.

2. DePuy Mitek is a corporation organized under the laws of the State of Massachusetts, with its corporate headquarters and principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts 02062.

3. Pearsalls repeats and realleges and incorporates herein by reference, paragraphs 12-23 of its Affirmative Defenses.

4. This is a claim arising under the Patent Laws of the United States, Title 35, United States Code, for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202. The jurisdiction of this Court is founded upon 28 U.S.C. §§ 1338(a), 2201 and 2202.

5. DePuy Mitek alleges that it is the owner of the '446 patent. There exists an actual controversy between Pearsalls and DePuy Mitek with respect to the validity, enforceability, scope and infringement of the '446 patent.

6. The '446 patent is not infringed, and further is invalid and unenforceable at least for the reasons set forth in paragraphs 14-23 of Pearsalls' Affirmative Defenses.

7. Pearsalls seeks a declaration by the Court that the '446 patent is not infringed, either directly or by inducement, by Pearsalls, that the '446 patent is invalid and unenforceable, and that DePuy Mitek, knowing that the '446 patent is invalid, not infringed by Pearsalls and unenforceable, while asserting the patent against Pearsalls, has committed patent misuse.

8. DePuy Mitek's conduct renders this an exceptional case within the provisions of 35 U.S.C. § 285, and Pearsalls is accordingly entitled to an award of attorneys' fees.

WHEREFORE, Pearsalls prays for judgment against DePuy Mitek as follows:

A. That the Court deny all relief to DePuy Mitek, and that the Amended Complaint be dismissed with prejudice;

B. That the Court decree, adjudge and declare that the '446 patent is invalid, not infringed by Pearsalls, directly or through inducement, and unenforceable and that DePuy Mitek has committed patent misuse by knowingly asserting an invalid and unenforceable patent against Pearsalls, with knowledge that Pearsalls does not infringe said patent;

C. That the Court find this an exceptional case and award reasonable attorney fees to Pearsalls under 35 U.S.C. § 285;

D. That the Court award Pearsalls its costs, and expenses; and

E. That the Court grant such further relief as it deems just and proper.



**JURY DEMAND**

Pearsalls demands a trial by jury on all issues triable to a jury with respect to its counterclaim.

Dated: October 14, 2005

Respectfully submitted,

By: s/Charles W. Saber

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Counsel for Defendants  
Arthrex, Inc. and Pearsalls Limited

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Pearsalls Limited's Answer and Counterclaim in Response to DePuy Mitek, Inc.'s Amended Complaint was electronically filed with the Court and served via the Court's email notification service on October 14, 2005, upon the following counsel for DePuy Mitek, Inc.:

Dianne B. Elderkin, Esq.  
Lynn A. Malinoski, Esq.  
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s/Salvatore P. Tamburo

# **EXHIBIT 19**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.  
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.  
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

**ARTHREX, INC.'S SECOND SUPPLEMENTAL OBJECTIONS AND RESPONSES  
TO DEPUY MITEK, INC.'S INTERROGATORY NOS. 3, 5, AND 7 AND  
ARTHREX'S SUPPLEMENTAL OBJECTIONS AND RESPONSE TO DEPUY  
MITEK, INC.'S INTERROGATORY NO. 6**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and Rule 33.1 of the Local Rules of the United States District Court for the District of Massachusetts, Defendant Arthrex, Inc., ("Arthrex") hereby provides second supplemental responses to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek's") Interrogatory Nos. 3, 5, and 7 of DePuy Mitek's First Set of Interrogatories and supplemental response to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek's") Interrogatory No. 6 of DePuy Mitek's First Set of Interrogatories. These supplemental responses are based on information reasonably available to Arthrex at the present time. Arthrex reserves the right to further supplement these responses when, and if, additional information becomes available, or known, to Arthrex. These interrogatories also remain premature to the extent that they

seek expert information. Such information will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order entered by the Court. Arthrex also reserves the right to object on any ground at any time to these Interrogatories. Arthrex further reserves the right to object on any ground to such other or supplemental Interrogatories DePuy Mitek may propound involving or relating to the subject matter of these Interrogatories.

### **GENERAL OBJECTIONS**

Arthrex incorporates herein the General Objections included in its Objections and Answers to DePuy Mitek's First Set of Interrogatories as if fully set forth herein.

### **DEFINITIONS**

Arthrex incorporates herein the Definitions included in its Objections and Answers to DePuy Mitek's First Set of Interrogatories as if fully set forth herein.

### **ANSWERS AND SPECIFIC OBJECTIONS**

The following Second Supplemental Responses to DePuy Mitek's Interrogatory Nos. 3, 5, and 7 and Supplemental Response to DePuy Mitek's Interrogatory No. 6 are made subject to and without waiver of the foregoing General Objections, and such General Objections are incorporated into each Response as though fully set forth therein. To the extent particular General Objections are restated in a Response, they are provided because they are particularly applicable to the specific Interrogatory and such inclusion is not to be construed as a waiver of any other General Objections.

#### **INTERROGATORY NO. 3.**

Describe all facts that support Arthrex's contentions that it has not infringed any claim of the Patent-in-Suit as set forth in ¶¶ 12-13 of Arthrex's Answer including, but not limited to,

(a) identifying each element of each claim of the Patent-in-Suit that Arthrex contends is literally absent from each Arthrex Braided Suture Product;

(b) explain (i) what Arthrex contends the basic and novel characteristics of the invention claimed in the Patent-in-Suit are; (ii) each contention that Arthrex does not infringe the Patent-in-Suit because its Braided Suture Products have a material that materially affects the claims' basic and novel characteristics; and (iii) what the material effect on the claims' basic and novel characteristics are by an alleged material in Arthrex's Braided Suture Products.

(c) explain any Arthrex contention that any alleged absent claim element is not satisfied under the doctrine of equivalents by describing all alleged substantial differences between the claim and Arthrex's Braided Suture Products and any reason why the function/way/result test is not satisfied for each Arthrex Braided Suture Product; and

example, Burgess in view of either one of U.S. Patent Nos. 4,563,392 or 4,543,286, both to Harpell et al. ("the Harpell patents"). Both of the Harpell patents disclose the use of UHMWPE in surgical suture applications. Had the Examiner known of the Harpell patents in August 1992, he would have maintained the rejection of claims 1 and 8 on § 103 grounds.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 as being unpatentable over Burgess and the Harpell patents in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

The above is not intended to be an exhaustive list of reasons why the '446 patent is invalid under 35 U.S.C. §§ 102, 103, but rather, it is intended to be only an exemplary list of such reasons.

#### **INTERROGATORY NO. 6.**

With respect to Arthrex's inequitable conduct defense and counterclaim:

- (a) identify all persons who allegedly committed inequitable conduct;
- (b) state all facts supporting Arthrex's contention that the such persons committed inequitable conduct; and
- (c) identify each piece of information that was allegedly withheld and each alleged misrepresentation and why the alleged withheld information or misrepresentation is material.

#### **RESPONSE**

Arthrex objects to this Interrogatory to the extent that it seeks information not yet in Arthrex's possession. Most of the facts surrounding the alleged inequitable conduct are known to the applicants of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, and their attorneys; and since discovery has

only just begun in this case, Arthrex has not yet had an opportunity to obtain all information responsive to this Interrogatory. Subject to and without waiving its general and specific objections, Arthrex answers:

- (a) At least the applicants of the '511 application and their attorneys, including Hal Brent Woodrow, committed the alleged inequitable conduct.
- (b) During prosecution of the '511 application, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from claim 21 of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bioabsorbable yarns.

The applicants and their attorneys misrepresented Kaplan as stating "in one embodiment, the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition." See Amendment filed August 4, 1993 at page 2. The applicants and their attorneys then immediately went on to state that claim 21 does not claim a sheath yarn composed of a bio-absorbable yarn. *Id.*

Their statements regarding Kaplan's teachings were entirely misleading, however. Kaplan actually states that "sheath component 34 may also be fabricated from individual filaments *having more than two different chemical compositions, one or more of which optionally being non-bioabsorbable.*" [Emphasis added.] Kaplan at column 9, lines 25-28. In other words, Kaplan discloses that the sheath component may be fabricated from individual filaments, all of which may be non-bioabsorbable.

The applicants and their attorney again misrepresented the teachings of Kaplan when they stated that "the sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments." See Amendment



filed August 4, 1993 at page 3. As described above, Kaplan does, in fact, disclose a sheath containing all non-bioabsorbable yarns.

(c) The mischaracterizations and misrepresentations made by the applicants and their attorneys were material since the Examiner ostensibly relied on them in deciding that the rejections based on Kaplan had been overcome and in allowing the '511 application after the Amendment was filed on August 4, 1993.

#### **SUPPLEMENTAL RESPONSE**

In addition to the above, Arthrex further responds that during the prosecution of the '511 application, applicants and their attorney, Matthew S. Goodwin, responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction, with polyester and/or nylon, would have poor qualities for a suture (e.g., poor knot strength, poor knot security, low elongation and poor knot sliding) and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys truly believed that high tensile polythene was included within their claimed invention, then they could not have honestly made these statements and representations to the examiner. Accordingly, in such circumstances, the applicants and their attorney made a material misstatement with intent to deceive the PTO.

#### **INTERROGATORY NO. 7.**

With respect to Arthrex's contentions that the asserted claims are invalid under 35 U.S.C. § 112 (Answer at Affirmative defenses ¶11):

(a) identify each claim of the Patent-in-Suit that is allegedly invalid under 35 U.S.C. § 112; and

Dated: January 27, 2006

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Counsel for Defendants Arthrex, Inc.  
and Pearsalls, Limited

**CERTIFICATE OF SERVICE**

It is hereby certified that a true and correct copy of the foregoing Arthrex, Inc.'s Second Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5 and 7 and Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 6 has been served by facsimile on the following counsel for DePuy Mitek, Inc. on this 27th day of January 2006:

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s/Salvatore P. Tamburo  
Salvatore P. Tamburo

# **EXHIBIT 20**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.  
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.  
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

**EXPERT REPORT OF JOHN F. WITHERSPOON**

**INTRODUCTION**

I have been asked by counsel for defendant Arthrex, Inc. (“Arthrex”) to serve as an expert consultant with respect to United States patent practices and procedures, both generally and as they relate to this case, and on various issues in the case. I understand that I may be called to present expert testimony at trial, including testimony in rebuttal, and I have been asked to prepare a written report with respect to that possible testimony. More specifically, I have been asked at this time to prepare a report setting forth (a) a general description of United States Patent and Trademark Office (“PTO”) practices and procedures, (b) a discussion of the prosecution history of United States Patent No. 5,314,446 (“the ‘446 patent”) here in suit, and (c) opinions specific to this case regarding certain issues for which Arthrex has the burden of proof.

I reserve the right to file a report in rebuttal to those filed on behalf of the plaintiff. I also reserve the right to supplement my report(s) so as to accommodate the discovery of any additional information that may impact my testimony and opinions.

### **BACKGROUND AND PROFESSIONAL EXPERIENCE**

1. I am a citizen of the United States and reside in Bethesda, Maryland.
2. I am an attorney in private practice in Washington, D.C., where I have practiced patent law for over thirty years. In addition, I served as an Examiner-in-Chief (a position now called “Administrative Patent Judge”) and as a member of the Board of Appeals (now named the Board of Patent Appeals and Interferences) in the PTO for seven and one-half years. Before entering private practice, I served for two years as a Law Clerk to Judge Giles Sutherland Rich of the United States Court of Customs and Patent Appeals (“CCPA”) a predecessor court to the United States Court of Appeals for the Federal Circuit (“Federal Circuit”).
3. From 1992-2004, I was Distinguished Professor of Intellectual Property Law and Coordinator or Co-Director of the specialty track in Intellectual Property Law at George Mason University School of Law in Arlington, Virginia, where I was a member of the part-time faculty and taught courses in patent law. In recognition of this work the law school faculty and University Provost unanimously voted to accord me the title “Professor and Director Emeritus, Intellectual Property Program, George Mason University School of Law.” From 1998-2000, I also served as an Adjunct Professor of Law at the Georgetown University Law Center in Washington, D.C.
4. I was nominated by the President of the United States and confirmed by the Senate to be an Examiner-in-Chief and a member of the then Board of Appeals of the

PTO. The Board of Appeals is a review tribunal within the PTO that by statute sits in panels of at least three members to hear appeals from adverse decisions of examiners. It reviews the record made during the examination of an application, receives briefs from counsel and examiners, conducts hearings, and prepares written opinions. The Board's decisions constitute final agency determinations with respect to substantive questions of patent law. They are reviewable only by the Federal Circuit or by the United States District Court for the District of Columbia, whose decisions in such cases are in turn reviewable by the Federal Circuit. My work as a member of the Board of Appeals required an understanding of patent specifications, including patent claims and how they should be construed, as well as an understanding and application of the pertinent statutes, precedents, rules, and other regulations regarding the requirements for patentability and the examination of patent applications for issuance of United States letters patents. While on the Board, I participated in deciding more than 1,500 appeals.

5. During my career in private practice, I have personally prosecuted hundreds of applications for patents and reviewed hundreds of prosecution histories of other applications. As part of this work, I have had occasion to review thousands of claims in patents and patent applications to determine their meaning, to compare them with the prior art and other claims, to compare them with patent specifications, or to compare them with accused products, processes, etc. For the past twenty-five years I have also served as a consulting and/or testifying expert in patent litigation.

6. I am admitted to practice law in the District of Columbia and before the Supreme Court of the United States, the United States Court of Appeals for the District of

Columbia Circuit and the United States Court of Appeals for the Federal Circuit. I am also registered to practice before the PTO.

7. I am a member of numerous bar associations and professional societies relating to patent law and to science, including the American Bar Association Section of Intellectual Property Law, the American Intellectual Property Law Association, the Federal Circuit Bar Association, the Patent and Trademark Office Society, the Giles Sutherland Rich American Inn of Court, the New York Intellectual Property Law Association, the American Association for the Advancement of Science, and the American Chemical Society. Over the years I have held leadership positions in a number of these organizations.

8. I have been a member of the Advisory Board of BNA's Patent, Trademark and Copyright Journal since 1979. I am the editor of a book by BNA entitled "Nonobviousness—The Ultimate Condition of Patentability," and I have written several published articles in the field of United States patent law and practice. In addition, I have presented lectures and speeches about United States patent law and practice throughout the United States and Europe, including to the Judicial Conferences of the CCPA and the Federal Circuit.

9. I did undergraduate and graduate studies at the University of Illinois, receiving a B.S. degree in 1955, an M.Ed. degree in 1958, and an M.S. degree in Chemistry in 1960. I received an L.L.B. degree (later changed to a J.D. degree) from Georgetown University Law Center in 1964.



10. A copy of my Curriculum Vitae, which lists my publications, and a listing of cases in which I have testified in the past four years are attached as Exhibits A and B, respectively.

### **DATA AND OTHER INFORMATION CONSIDERED**

11. In preparing this report, I reviewed the following materials:

- a) U.S. Patent No. 5,314,446 in the names of Alastair W. Hunter, Arthur Taylor, Jr. and Mark Steckel ("the '446 patent");
- b) Prosecution history of the '446 patent;
- c) U.S. Patent Nos. 4,543,286 ("Harpell *et al.* '286"); 4,563,392 ("Harpell *et al.* '392"); 4,610,688 ("Silvestrini *et al.*"); 5,120,802 ("Mares *et al.*"); and 5,318,575 ("Chesterfield *et al.*");
- d) U.K. Patent Application 2 218 312 A ("Burgess");
- e) Brochure designated Dyneema SK60 ("the Dyneema brochure") (Bates Nos. PR 08420-429);
- f) Article by Cohan *et al.* entitled "An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture" ("Cohan *et al.*") (Bates Nos. ARM 25132-137);
- g) DePuy Mitek's Responses to Arthrex, Inc.'s First Set of Interrogatories; DePuy Mitek's Supplemental Responses to Arthrex, Inc.'s First Set of Interrogatories; DePuy Mitek's Responses to Arthrex, Inc.'s Second Set of Interrogatories; DePuy Mitek's Second Supplemental Responses to Arthrex, Inc.'s First Set of Interrogatories; and DePuy Mitek's Second Supplemental Responses to Arthrex, Inc.'s Interrogatory No. 15;
- h) Arthrex, Inc.'s Objections and Answers to DePuy Mitek, Inc.'s First Set of Interrogatories; Arthrex, Inc.'s Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 2, 4, 10 and 12; Arthrex, Inc.'s Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5 and 7; Arthrex, Inc.'s Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 1; Arthrex, Inc.'s Second Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5, and 7 and Arthrex's Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 6; Arthrex, Inc.'s Objections and Response to DePuy Mitek, Inc.'s Second Set of Interrogatories to Arthrex, Inc.; and Pearsalls, Limited's

Objections and Response to DePuy Mitek, Inc.'s Second Set of Interrogatories to Pearsalls, Limited;

- i) Transcripts of depositions of Dr. Mark G. Steckel given on January 26 and January 27, 2006; Dennis J. Jamiolkowski given on November 30, 2005; Hal Brent Woodrow given on November 2, 2005; and Matthew Goodwin given on January 17, 2006;
- j) Portions of laboratory Book No. 2175, issued to Mark Steckel (Bates Nos. DMI002605-2678);
- k) Documents bearing Bates Nos. DMI095015-5042;
- l) Five page document entitled DePuy Mitek's Privileged Document List, dated January 23, 2006;
- m) Discussion with Dr. Debi Prasad Mukherjee; and
- n) Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent No. 5,314,446.

#### **BASES FOR TESTIMONY AND OPINIONS**

12. The bases for my testimony and opinions are the materials identified above; my background, training, and over forty-three years of working experience in the field of patent law and practice, including my knowledge of and experience with the practices and procedures of the PTO, acquired in part during the more than seven years that I served as a member of the PTO Board of Appeals; the patent statutes; case decisions; the PTO rules of practice as set forth in Title 37 of the Code of Federal Regulations (37 CFR); and the PTO Manual of Patent Examining Procedure ("MPEP"). My testimony may also be based, in part, on the testimony and discussions with other witnesses (both expert and fact) and associated documentation in this case.

## GENERAL CONSIDERATIONS

### **The Parts of Patent Applications and Patents**

13. A patent is a legal document issued by the federal government that reflects a kind of bargain between an inventor and the public. The inventor must have made an invention that satisfies certain legal requirements and must disclose the invention in accordance with certain legal standards. The public, in turn, grants to the patent owner the right to exclude others from practicing the invention during the term of the patent. Contrary to popular belief, a patent does not grant to the patent owner the right to practice the invention.

14. Patents are directed to one of four statutory classes of subject matter that qualifies for patent protection—(1) process, (2) machine, (3) manufacture, and (4) composition of matter. Thus, also contrary to popular belief, patents do not protect concepts or ideas. Rather, they pertain to the “useful arts”—the term used in the Constitution.

15. A patent or patent application consists of two main parts: a “written description” and one or more “claims.” The two parts constitute the *quid* and the *quo* of the bargain.

16. The written description, sometimes called the specification, explains what the invention is, how it is made, how it is used, and the best mode of carrying out the invention, all in sufficient detail that the public (*i.e.*, persons skilled in the art to which the invention pertains) is able to understand and practice the invention without undue experimentation. Drawings, charts and/or graphs are often used to help explain what is

being described. The “written description” part of a patent is basically a teaching document. Its purpose is to satisfy the inventor’s part of the bargain with the public.

17. In contrast, the claims of a patent are legal instruments that define the scope of the patent owner’s exclusive rights. Each claim is a separate instrument. It is a single sentence comprising a list of words and phrases (known as claim “elements” or “limitations”) which together make up the claim. A claim must be reviewed in its entirety or, as is sometimes said, “as a whole.” Every patent must have at least one claim. Claims appear at the very end of the patent and, if there is more than one, the claims are numbered. According to the Supreme Court, the construction of a patent, “including terms of art within its claims,” is exclusively within the province of the court.

18. A more detailed discussion of claims is set forth in Exhibit C.

### **The Examination of Patent Applications in the PTO**

19. The PTO is an agency within the United States Department of Commerce. It is physically located in Alexandria, Virginia. It is fully funded by fees paid by its users, including applicants for patents and owners of issued patents. The principal responsibility of the PTO with respect to its patent operation is to examine patent applications to determine whether they should issue as patents. The governing authorities, in decreasing order of importance, are the statutory provisions set forth in Title 35 of the United States Code (35 USC), court decisions, the codified Patent Rules of Practice set forth in Title 37 of the Code of Federal Regulations (37 CFR), and the Manual of Patent Examining Procedure (MPEP), which sets forth additional guidelines and instructions to examiners.

20. The PTO currently employs about 4000 patent examiners, each of whom is assigned to a particular class or specialty of technology corresponding to the individual

examiner's science or engineering degree and/or work experience, if any. Generally speaking, examiners have an undergraduate degree (a limited number having an advanced degree) in some field of science or engineering, but little or no actual experience working in the field. They are therefore normally not persons skilled in the art to which they are assigned. However, they are assumed to have some expertise in interpreting prior art references and to be familiar from their work with the level of skill in the art. The patent applications on an examiner's docket normally fall within the subclass or specialties assigned to that examiner. Some examiners are lawyers, but many are not.

21. In examining a patent application an examiner is expected first to obtain an understanding of the application and claimed invention and then search the most relevant prior art available to the examiner. The "prior art" under United States law is very extensive. It includes all patents throughout the world, all printed publications throughout the world (which may include electronic publications and websites), and all prior public use activity, on sale activity, public knowledge by others, and inventions by others in the United States.

22. Prior art in the form of trade literature, sales brochures, some scientific publications, and some foreign patents are generally not available to examiners. The same is true with respect to prior public knowledge, prior public uses, prior sales and offers for sale of products in commerce, and prior inventions of others. Examiners do not have the benefit of technical experts or other workers in the field with whom to consult. Nor do examiners have the benefit of laboratories with which to carry out experiments to verify the accuracy and completeness of statements made in a patent specification, in affidavits and declarations, and in arguments made during prosecution of the application.

23. The examination of patent applications is *ex parte* in nature; the public does not participate. Historically, patent applications and their examinations (subject to a few limited exceptions) were required by statute to be kept in confidence. (Legislation enacted in 1999 now provides for the automatic publication of many applications after eighteen months.) Generally speaking, each examiner has many (typically over a hundred) patent applications on his or her docket at any given time, and therefore has a limited time to devote to each patent application.

24. The examination of an application in the PTO usually entails a multi-stage process of submission, rejection by the examiner accompanied by commentary explaining the reasons for the rejection, response by the applicant, etc. An applicant's response often entails amending claims to narrow their scope in an attempt to avoid prior art. Applicants also frequently present arguments as to why their claims are patentable over the prior art. Evidence in the form of an affidavit or declaration is sometimes submitted by the applicant.

25. PTO regulations permit interviews between examiners and applicants, their attorneys or agents. Such interviews may be in person in an examiner's office or by telephone.

26. The exchanges between an applicant and the examiner constitute what is called "patent prosecution." Historically, the patent prosecution papers have been maintained in the PTO in a folder called a "file wrapper". In recent times an electronic copy of these papers, as well as an electronic copy of the application papers themselves, make up what is called an "image file wrapper" or IFW. In either case, these materials constitute the official record of a patent's history. The prosecution history may be an important instrument in determining the scope of an issued patent.

27. 37 CFR § 1.56 (1992), commonly referred to as PTO “Rule 56,” reads in part as follows:

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section...

28. Examiners expect and rely on inventors and their attorneys or agents to be truthful and to act with candor and good faith in dealing with the PTO, as required by the PTO regulations and case decisions. The duty applies to all individuals associated with the filing or prosecution of an application. These individuals have a duty to disclose information known to one or more of them to be material to patentability. Examiners expect and rely on them to comply with this duty. There are several reasons for these expectations. First, as discussed above, an examiner does not have access to all prior art. Nor does an examiner have an opportunity to verify the accuracy of representations of fact known only by the inventor. Second, an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, may mislead an examiner into granting a patent which does not meet the legal criteria. The duty of disclosure includes a duty to tell an examiner of an erroneous material representation, when discovered, during PTO proceeding.

29. Normally material prior art is called to an examiner’s attention by filing a document known as an Information Disclosure Statement (“IDS”). However, such

information may also be called to an examiner's attention in the remarks section of a response to an Office Action or in the patent application itself.

30. Prior to March 16, 1992, Rule 56 defined material information as information as to which there is a substantial likelihood a reasonable examiner would consider the information important in deciding whether to allow the application. Since March 16, 1992, Rule 56 has provided that information is material when it is not cumulative to information already of record and (1) establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) refutes, or is inconsistent with, a position the applicant takes in either opposing an argument of unpatentability or asserting an argument of patentability.

31. The MPEP is an official publication of the PTO that is intended to provide patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the PTO. Section 2004, entitled "Aids to Compliance With Duty of Disclosure" sets forth suggestions for complying with the duty of disclosure. Among things to be considered are: "the origin of the invention and its point of departure from what was previously known and in the prior art;" "possible public uses and sales;" and "prior publication, knowledge, patents, foreign patents, etc." Section 2004 also emphasizes that "[c]are should be taken to see that prior art or other information cited in a specification or an information disclosure statement is properly described and that the information is not incorrectly or incompletely characterized." It is further pointed out that "[w]hen in doubt, it is desirable and safest to submit information," since "[e]ven though the attorney, agent, or applicant doesn't consider it necessarily material, someone



else may see it differently and embarrassing questions can be avoided.” In this regard, the Manual points out that one district court has stated: “In short, the question of relevancy in close cases, should be left to the examiner and not the applicant.” The Manual also notes that “[i]t may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention.” Thus the MPEP strongly suggests erring on the side of disclosure. (The quoted passages from the MPEP appeared in the Manual throughout the pendency of the application leading to the ‘446 patent.)

32. The duty of inventors and their attorneys or agents to disclose material information is a continuing duty that runs throughout the entire pendency of a patent application.

33. In reviewing an application, an examiner is expected to determine whether the specification contains a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which the invention pertains to make and use the invention without undue experimentation. To the extent possible, he or she also reviews the application to see whether the best mode contemplated by the inventor of carrying out her invention is disclosed. These requirements are sometimes called (1) the “written description” requirement, (2) the “enablement” requirement, and (3) the “best mode” requirement.

34. An examiner is expected to understand that the test for the written description requirement is whether the disclosure of the application reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter at the time the application was filed and that the test for the enablement requirement is whether the

specification, viewed from the perspective of a person skilled in the art, teaches such a person how to make and use the claimed subject matter without having to resort to undue experimentation.

35. In determining compliance with the “written description” and “enablement” requirements, an examiner is expected to understand that a broad or generic term found in a specification does not necessarily cover any and all technology that might otherwise seem to be embraced by the term. One must also consider the context in which the term is used. For example, if the specification indicates that the technology designated by the term must possess certain characteristics or properties, then things that do not possess those characteristics or properties should not be deemed to be “described” or “enabled” simply because the term is used.

36. An examiner is expected to determine whether a patent specification concludes with one or more claims which particularly point out and distinctly claim the subject matter that the applicant regards as his invention. This requirement is sometimes called the requirement for “definiteness”. In doing so, an examiner is expected to consider that a claim should set out and circumscribe a particular area with a reasonable degree of precision and particularity. The definiteness of claim language must be analyzed in light of the teachings of the prior art and of the disclosure in the specification as it would be interpreted by a person possessing the ordinary level of skill in the pertinent art. An examiner would be expected to understand that the principal sources for construing claims is the language of the claim and the disclosures of the specification, and that transitional terms such as “comprising”, “consisting of”, and “consisting essentially of” should be construed according to their well-established meanings in the law.

37. An examiner is expected to determine whether a claim is directed to subject matter that is new relative to the prior art. In doing so, an examiner is expected to recognize that a claim is not directed to new subject matter if a single item of prior art anticipates, *i.e.*, identically discloses each element of the claimed invention in the claimed relationship.

38. An examiner is expected to determine whether a claim is directed to subject matter that, although novel, satisfies the requirement for nonobviousness. In doing so, an examiner is expected to consider the level of skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed invention. Against this background, the examiner is expected to determine whether the subject matter of the claim as a whole would have been nonobvious to a person having ordinary skill in the art at the time the invention was made. Any “secondary” consideration evidence submitted by an applicant must be taken into account. Such evidence is sometimes presented in a declaration or affidavit. Examples of secondary considerations indicative of the nonobviousness of a claimed invention are long felt need, prior attempts and failures, acceptance by others, including copying, simultaneous developments, and commercial success. The results achieved by an invention may also constitute evidence of nonobviousness if they are unexpected, *i.e.*, not taught or suggested by the prior art.

39. An examiner is expected to understand that prior art documents are deemed to be addressed to persons of ordinary skill in the pertinent art, and that for purposes of evaluating nonobviousness issues, a prior art document should be considered from the standpoint of what it teaches or suggests to one having the knowledge of a person of ordinary skill in the art. Obviousness is to be determined as of the time the invention was made or one year prior to the filing date. An examiner is also expected to understand that

a conclusion of obviousness cannot properly be made unless the state of the art is such as to provide a motivation or reason for the person of ordinary skill to combine the teachings of the prior art.

40. The practice of combining the teachings of two or more prior art “references” can be illustrated as follows: Suppose an examiner is reviewing a patent application claiming a chair that has rollers. The examiner finds a prior patent or printed publication that discloses a chair without rollers. The examiner finds another prior patent or printed publication that discloses a piano that has rollers and explains that the rollers make the piano easier to move. The examiner rejects the claim before her as not being in compliance with the requirement for nonobviousness. In doing so, the examiner reasons that it would have been obvious to a person of ordinary skill in the furniture art, in view of the combined teachings of the two references (which the hypothetical person of ordinary skill in the art is presumed to know), to modify the prior art chair by making it with rollers, and that when so modified one obtains the subject matter being claimed. The examiner also explains that the motivation or reason for modifying the prior art chair in this manner is provided by the knowledge of the person having ordinary skill that rollers make the piano easier to move. Indeed, in this simple example the examiner alternatively might reason that one skilled in the art would be motivated to modify the prior art chair by making it with rollers, because rollers are well known generally to workers in the art (even to lay people) to make things such as furniture easier to move; however, the piano reference reinforces this contention considerably.

41. Since the examination of a United States patent application is an *ex parte* proceeding, an examiner need only establish a *prima facie* case of obviousness in order to

shift the burden of going forward to the applicant. In his response, an applicant may challenge whether a *prima facie* case has been established or, alternatively, attempt to overcome the *prima facie* case by submitting evidence in affidavit or declaration form which purports to demonstrate nonobviousness of the claimed subject matter. This evidence may include test data or experimental results obtained from a comparison of the claimed subject matter with the prior art. All relevant data must be disclosed. It is not proper to submit to the PTO only favorable results and withhold unfavorable results because to do so would be misleading.

42. An examiner is expected to understand that under certain circumstances an applicant is entitled to bring forward evidence (in the form of declarations or affidavits) establishing a date of invention prior to the application's filing date, and thereby overcome (*i.e.*, antedate) one or more prior art references. This may be done by proving a conception and an actual reduction to practice of the claimed invention prior to the effective date of the reference. The determination of the date of an invention is claim specific. Conception is defined as the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. Normally the only corroboration required is of the formation of the idea or concept by the inventor. The invention is regarded to have been actually reduced to practice when the concept has been embodied in some physical form that contains every limitation of a claim and that is demonstrated to be a workable embodiment. In some instances, laboratory testing of a physical embodiment may be sufficient to demonstrate its workability for its intended purpose or use. In other instances, testing under commercial or actual conditions of intended use may be required to establish actual reduction to practice. Normally

corroboration must be provided in the form of direct or circumstantial evidence that the embodiment of the invention was constructed and was demonstrated to work successfully. This can include testimony of a co-employee with first hand knowledge of the work done. Conception determines “who” made the invention and controls the question of inventorship, whereas reduction to practice determines “when” the invention was made.

### **TESTIMONY SPECIFIC TO THIS CASE**

#### **Preliminary Remarks**

43. I understand that the claims of the ‘446 patent being asserted in this litigation are independent claim 1 and dependent claims 2, 8 and 12 (“the asserted claims”). I also understand that the parties disagree as to the meaning of the term “PE” that appears, directly or indirectly, in all of the asserted claims. More specifically, I understand that the parties disagree as to whether ultra high molecular weight polyethylene (“UHMWPE”) is within the scope of the claims. Finally, I understand that the Court has yet to resolve this dispute.

#### **Prosecution History**

44. I expect to explain the prosecution history of the ‘446 patent. More specifically, I expect to testify regarding the events that occurred during the prosecution by identifying and discussing in varying degrees certain of the papers appearing in the file history. More specifically yet, I expect to explain what prior art and other information was and was not considered by the examiner, what objections, rejections and statements were made by the examiner, and what responses and amendments were made by the applicants. This testimony would be essentially descriptive and explanatory in nature, and include at least some of the following points.

45. On February 19, 1992, an application for patent entitled “Sterilized Heterogeneous Braids” was filed in the PTO in the names of Alastair W. Hunter, Dennis D. Jamiolkowski, Arthur Taylor, Jr. and Mark Steckel. It was assigned application No. 07/838,511. It contained three sheets of drawings, which included three Figures. It contained twenty-four claims, claims 1-20 being directed to a “heterogeneous braid” and claims 21-24 being directed to a “surgical suture.”

46. The Declaration accompanying the application and which was signed by the four named inventors contains the following statements:

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

47. On the same day, an Information Disclosure Statement was filed which identified eleven references, five of which were said by Mr. Goodwin to have been discussed in the Background of the Invention. Mr. Goodwin also stated that the additional six references “may be relevant” to the examination of the application. In doing so, he had this to say with respect to one of them:

U.K. Patent Application GB 2 218 312A [Burgess], discloses a fishing line of braided construction, some braid filaments being composed of polythene and other filaments composed of polyester and/or nylon.

48. On July 8, 1992, the examiner required restriction between “claims 1-20, drawn to a heterogeneous braid” and “claims 21-24, drawn to a surgical suture,” saying that the two groups of claims “are related as mutually exclusive species in intermediate-final product relationship.” The examiner explained that distinctness “is proven for

claims in this relationship if the intermediate product is useful to make other than the final product...and the species are patentably distinct....” Further, the examiner explained that “in the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.” In a telephone conversation, Mr. Goodwin made a provisional election of claims 21-24, *i.e.*, the claims drawn to a surgical suture.

49. In the same Office Action, the examiner rejected claims 21-24 under 35 U.S.C. 103 as being unpatentable over Burgess. On August 6, 1992, Mr. Goodwin mailed a response to the PTO in which he sought to refute the examiner’s rejection and underlying reasoning.

50. In the next Office Action, dated November 2, 1992, the examiner dropped his rejection based on Burgess. In responding to the Office Action, on December 2, 1992, Mr. Goodwin stated that:

Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants’ response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

51. On March 18, 1993, the examiner continued to reject all claims, but not on Burgess. On August 4, 1993, a new attorney, Mr. Woodrow, mailed to the PTO an Amendment in which application claim 21 was amended. Amended claim 21 became claim 1 of the ‘446 patent. On the same day, Mr. Woodrow mailed an IDS. The IDS called the examiner’s attention to five U.S. patents and one British patent.



52. The application was allowed on November 18, 1993, and it issued on May 24, 1994 as the '446 patent.

### **Specific Opinions and Conclusions**

53. Based upon my study of this case to date, I have formed the following opinions and reached the following conclusions.

54. If the term "PE" in the asserted claims of the '446 patent is construed by the Court to include ultra high molecular weight polyethylene ("UHMWPE"), then they are invalid for failing to satisfy the written description and enablement requirements of the first paragraph of 35 U.S.C. 112. (Since dependent claims 2, 8 and 12 do not limit claim 1 with respect to the term PE, they are subject to the same claim construction and are invalid under this claim construction for the same reasons that apply to claim 1.) The bases for my opinion include the principles set forth in paragraphs 33-35, *supra*, and the expected testimony of Dr. Mukherjee as set forth in his Report.

55. If the term "PE" in the asserted claims of the '446 patent is construed by the Court to include UHMWPE, then they are invalid for failing to satisfy the novelty requirement because they are anticipated by Chesterfield *et al.* I understand that the plaintiff contends that the invention of the '446 patent was reduced to practice "at least as early as February 2, 1989" (Supp. Resp. to Int. No. 6) *i.e.*, three years before the February 3, 1992 filing date of Chesterfield *et al.* I disagree. I find no evidence that a "surgical suture," as required by each asserted claim, was constructed. I find no evidence that "a sterilized, braided construction," as required by each asserted claim, was built before the effective date of the reference. Furthermore, the braided structures that were built appear to have experienced substantial problems with core popping and braid

looseness. And in a handwritten note dated February 9, 1990, Dr. Schwartz specifically referred to “technical problems of mixing 2 materials with dissimilar stress/strain properties.” (Bates No. DMI095020.) This notation is entirely consistent with the fact that I have seen no evidence indicating that these problems had been solved prior to February 2, 1989. Nor have I seen evidence that they had been solved prior to the February 19, 1992 filing date of the ‘446 patent. Under the circumstances, Chesterfield *et al.* is a prior art reference under 35 U.S.C. 102(e). The bases for my opinion include the principles set forth in paragraphs 37 and 42, *supra*, and the expected testimony of Dr. Mukherjee as set forth in his Report both with respect to the disclosure of Chesterfield *et al.* and the lack of proof of a reduction to practice.

56. If the term “PE” in the asserted claims of the ‘446 patent is construed by the Court to include UMHWPPE, then they are invalid for failing to satisfy the nonobviousness requirement of 35 U.S.C. 103 in view of the following prior art references: Burgess, the Dyneema brochure, the Cohan *et al.* article, and Harpell *et al.* ‘286 and ‘392. The bases for my opinion include the principles set forth in paragraphs 38-40, *supra*, and the expected testimony of Dr. Mukherjee as set forth in his Report.

57. Regardless of whether the Court construes the term PE to include UHMWPE, I would expect to testify that the asserted claims are invalid for failing to satisfy the nonobviousness requirement of 35 U.S.C. 103 in view of Silvestrini *et al.* and the ‘802 patent to Mares *et al.* The bases for my opinion include the principles set forth in paragraphs 38-40, *supra*, and the expected testimony of Dr. Mukherjee as set forth in his Report.

58. If the term “PE” in the asserted claims of the ‘446 patent is construed by the Court to include UHMWPE, then I would expect to testify that Dr. Steckel, and Mr. Hunter, and/or Mr. Goodwin may have violated their duty to disclose material information to the PTO, as required by Rule 56. The bases for my opinion include the principles set forth in paragraphs 27-32, *supra*, the deposition testimony of Dr. Steckel, the deposition testimony of Mr. Goodwin, the arguments by Mr. Goodwin in his response mailed on August 6, 1992, as set forth in paragraph 49, *supra*, and the January 23, 2006 privileged document list. A more specific discussion is set forth below.

59. According to Dr. Steckel, he and at least co-inventor Hunter conceived of a braid construction made up of two dissimilar materials for use as a surgical suture, and that one such construction that they contemplated was the combination of UHMWPE (specifically, Spectra or Dyneema) and PET. Mr. Goodwin and Dr. Steckel jointly prepared the ‘511 application that ultimately led to the ‘446 patent. I understand that Dr. Steckel was Mr. Goodwin’s principal contact with respect to the preparation and prosecution of the ‘446 patent and that materials during prosecution were sent to Mr. Hunter.

60. As discussed in paragraph 49, *supra*, the examiner rejected claims 21-24 (all claims then being examined) as being unpatentable over Burgess. Burgess contains the following disclosure:

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost

perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

61. In responding to this rejection, Mr. Goodwin represented to the examiner that if a medical designer were to actually build a surgical suture using the braided combination of UHMWPE and polyester, then “he would inevitably design an unacceptable suture.” In his response, Mr. Goodwin also represented to the examiner that the braided combination disclosed in Burgess would have “poor knot strength properties.”

62. Dr. Steckel’s testimony regarding the use of UHMWPE in a braided suture is the opposite of what Mr. Goodwin represented to the examiner. Dr. Steckel also testified that he and Mr. Hunter discussed braiding UHMWPE and polyester prior to the filing date of the ‘511 application and that they believed it would lead to an acceptable suture. Further, Dr. Steckel testified that at the time he considered such a combination to be “a good idea” and that braiding UHMWPE and polyester together would result in “improved knot strength.”

63. In my opinion, the arguments presented to the examiner with respect to alleged distinctions between the claimed invention (assuming the claims include UHMWPE) and Burgess are inconsistent with Dr. Steckel’s testimony. It is also my opinion that, accepting Dr. Steckel’s testimony as true, the representations made to the examiner are misrepresentations in highly material respects, because they were made for the purpose of overcoming a prior art rejection in order to obtain the allowance of claims for issuance in a patent.

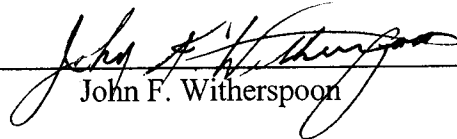
### EXHIBITS

64. I have not at this time prepared any exhibits which I expect to use as summary of or support for my opinions. However, I would expect to use during my testimony at trial at least some of the documents listed above under "Information Considered". I may also use demonstrative exhibits, summaries, or other exhibits that are not yet prepared, to further illustrate my testimony. I understand that such exhibits would be exchanged with opposing counsel at a time to be mutually agreed upon or required by the Court.

### COMPENSATION

65. I am being compensated for my work on this case at my customary rate of \$600 per hour, plus expenses. My compensation is not based on the outcome of the litigation.

March 3, 2006

  
John F. Witherspoon

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Expert Report of John F. Witherspoon was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 3rd day of March 2006:

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s/Salvatore P. Tamburo